

DRI® Hydrocodone Assay Calibrators and Controls

IVD For In Vitro Diagnostic Use

Rx Only

REF 1664	DRI Negative Urine Calibrator 0 (1 x 10 mL)
1388	DRI Negative Urine Calibrator 0 (1 x 25 mL)
10018079	DRI Hydrocodone Assay Calibrator 100 (1 x 10 mL)
10018080	DRI Hydrocodone Assay Calibrator 300 (1 x 10 mL)
10018081	DRI Hydrocodone Assay Calibrator 500 (1 x 10 mL)
10018082	DRI Hydrocodone Assay Calibrator 1000 (1 x 10 mL)
10018149	DRI Hydrocodone Assay Control Kit (2 x 10 mL)

Intended Use

The DRI® Hydrocodone Assay calibrators are intended for the calibration of the DRI Hydrocodone Assay. The DRI Hydrocodone Assay Controls are used to validate the DRI Hydrocodone Assay calibration. For In Vitro Diagnostic Use Only.

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Description of DRI Hydrocodone Calibrators and Controls

The DRI Hydrocodone Assay Calibrators and controls are liquid and ready-to-use. They are prepared by spiking known quantities of Hydrocodone into a drug-free negative human urine matrix. The DRI Hydrocodone 300 ng/mL calibrator can be used as a qualitative cutoff reference for distinguishing "positive" from "negative" samples. An estimate of drug concentration in the samples can be obtained by running a standard curve using all five calibrators and by estimating sample concentrations off the standard curve.

Each Calibrator is sold separately and may be used with any reagent lot.

The control kit is sold separately. Each laboratory should establish its own acceptable control ranges.

Tables 1 & 2: Hydrocodone concentrations in DRI Hydrocodone Calibrators and Control kit.

Table 1

Calibrators	Concentration (ng/mL)
Negative	0
100	100
300	300
500	500
1000	1000

Table 2

Controls	Concentration (ng/mL)
Low	225
High	375

⚠ Precautions and Warning

The DRI Hydrocodone Calibrators and Controls are harmful if swallowed.

The calibrators and controls are prepared from non-sterile human urine. **Handle the calibrators and controls as if they were potentially infectious.**

The calibrators and controls contain ≤0.2% bovine serum albumin (BSA) and ≤0.09% sodium azide. Avoid inhalation and contact with skin and mucous membrane. May cause skin or inhaled allergic reaction. Refer to Safety Data Sheet (SDS) for additional precautions, handling instructions, and accidental exposure treatment.

In the case of accidental spill, clean and dispose of material according to your laboratory's standard operating procedure, local, and state regulations.

Do not use the calibrators or controls beyond the expiration dates printed on the respective labels. If packaging is damaged on arrival, contact the technical support representative.

Calibrators and Controls Preparation and Storage

The DRI Hydrocodone Calibrators and Controls are liquid, ready-to-use. The calibrators and controls should be stored refrigerated at 2° to 8°C when not in use. The calibrators and controls are stable until the expiration date indicated on the bottle label. Once opened the calibrators and controls are stable for 60 days when stored at 2° to 8°C. Do not use calibrators and controls beyond the expiration date.

Assay Procedure

For instructions, refer to the instrument specific application sheets for the DRI Hydrocodone Assay.

Results and Expected Values

Qualitative Results

The 300 ng/mL calibrator can be used as a cutoff reference for distinguishing "positive" from "negative" samples. A sample that exhibits a change in absorbance value (Δ) equal to or greater than that obtained with cutoff calibrator is considered as positive. A sample that exhibits a change in absorbance value (Δ) lower than that obtained with the cutoff calibrator is considered as negative. The controls should be used in parallel to verify the assay. The results of the controls should be within the range established by each laboratory.

Semi-Quantitative Results

An estimate of drug concentrations in the samples can be obtained by running a standard curve with all five calibrators and estimating sample concentrations off the standard curve. Sample results above the high calibrator should be diluted with negative urine and retested.

Quality Control

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Limitations

The DRI Hydrocodone Calibrators and Controls are designed for use with the DRI Hydrocodone Assay for the detection of Hydrocodone and its metabolites in human urine.

References

DRI Hydrocodone Assay Package Insert.

Glossary:

<http://www.thermofisher.com/symbols-glossary>



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